



22 CFR Part 135

[Public Notice: 11951]

RIN 1400-AF52

Implementation of HAVANA Act of 2021

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: This rule finalizes the initial implementation by the Department of State (the Department) of the HAVANA Act of 2021. The Act provides authority for the Secretary of State and other agency heads to provide payments to certain individuals who have incurred qualifying injuries to the brain. As noted in the interim final rule (IFR) published in June 2022, this rulemaking covers current and former Department of State employees, and dependents of current or former employees. This final rule responds to public comments and amends four provisions in the IFR, adding two additional certification Boards for physicians who can sign the Form DS-4316; clarifying the definition of “qualifying injury to the brain;” and adding approval for Social Security Insurance (SSI) benefits as one of the eligibility criteria for a Base Plus payment.

DATES: *Effective date:* This final rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Jenifer Moore, Advisor, Health Incident Response Task Force, email: HIRTFstaffers@state.gov, telephone number: 202-647-5010.

SUPPLEMENTARY INFORMATION: This rule implements the Helping American Victims Affected by Neurological Attacks (HAVANA) Act of 2021, Public Law 117-46, codified in 22 U.S.C. 2680b(i), which (among other things) required Department heads to publish implementing rules. The Department published an IFR on June 30, 2022 (87 FR 38981), which laid out the process for HAVANA Act claimants in a new 22 CFR part 135, and provided that

physicians certified by the American Board of Psychiatry and Neurology (ABPN) could certify the Form DS-4316, *Eligibility Questionnaire for HAVANA Act Payments*. The IFR provided for 30 days of public comment. Based on some of the prevalent comments, the Department published a supplemental IFR on August 9, 2022 (87 FR 48444), which provided that physicians certified by the American Board of Physical Medicine and Rehabilitation (ABPMR) could certify the Form DS-4316. Both the IFR and supplemental IFR were effective August 15, 2022.

Further background is contained in the preamble to the IFR.

Responses to Comments

The Department received a total of 69 public comments in response to the IFR. Comments provided feedback under nine general categories: clinician criteria; date of injury restriction; imaging/magnetic resonance imaging scan (MRI) studies; “other incident;” length of qualifying medical treatment; payment eligibility criteria; qualifying injury definition; personal experience; and other. Many comments provided input on multiple subjects. Such comments were assigned to multiple categories. All comments are addressed in the aggregate below.

1. Clinician criteria: Thirty comments challenged the clinician certification required to determine a qualifying injury to the brain. They stated that the requirement to be diagnosed by a board-certified neurologist from the American Board of Psychiatry and Neurology (ABPN) was too narrow, and that other certifications and physician specialties should be considered.

As noted above, the Department accepted these comments and submitted a supplementary IFR to modify the provision of the IFR relating to the Board certification of the physician who is required to assess and diagnose an individual’s qualifying injury to the brain and complete the Form DS-4316. In addition to the ABPN and the ABPMR, through this final rule, the Department provides that physicians currently certified by the American Osteopathic Board of Neurology and Psychiatry (AOBNP) and the American Osteopathic Board of Physical Medicine and Rehabilitation (AOBPMR) may certify the Form DS-4316. The regulatory text (§ 135.3) and the DS-4316 are being amended accordingly.

2. Date of Injury Restriction: Fifteen comments focused on the date of injury, all expressing a belief that people who were affected by an anomalous health incident (AHI) earlier than January 1, 2016, should be eligible for a payment. The Department is unable to accept this suggestion. The HAVANA Act specifies that payments are for incidents occurring on or after January 1, 2016. The Department may not broaden the eligibility date without an amendment to the HAVANA Act or additional legislative action authorizing additional eligibility timeframes.

3. Imaging/MRI Studies: Nine comments raised objections to what was perceived as a blanket requirement for imaging/MRI studies that supported a diagnosis of “acute injury to the brain.” This perception is not correct. An individual may submit an MRI or other imaging studies to the certified physician to demonstrate an acute injury to the brain, but that is not the only way to demonstrate a qualifying injury under the IFR. The IFR also permits individuals to submit electroencephalogram (EEG) results, physical examination results, or other appropriate testing results to their certified physician for use in their physician’s assessment. The Department is adding an “or” between “EEG” and “physical examination” in the definition of “Qualifying injury to the brain” (§ 135.2), between paragraphs (2)(i) and (ii), to clarify the language, and is also amending Question 3 on the Form DS-4316 accordingly.

4. “Other Incident”: Seven comments noted that the language of the HAVANA Act regarding the occurrence of the injury (“in connection with war, insurgency, hostile act, or other incidents designated by the Secretary of State”) was very broad. With regard to “other incidents”, the commenters stated that this language makes the determination subjective and not measurable, and asked how those who would be denied would know that the decision was made using objective criteria. One commenter expressed concern over who would determine that an “attack” had occurred.

The definition of “other incident” in the IFR is: “A new onset of physical manifestations that cannot otherwise be readily explained.” For each request for payment, the Department will review available information on the reported incident, including any investigations that may have

been conducted. If the reports and the results of investigations do not provide a credible alternate explanation for the incident, that incident will be recommended for designation by the Secretary of State or their designee. Incidents for which an explanation has been identified will not be recommended for designation.

The list of reported incidents will be administratively controlled and will not be made public in order to ensure privacy for everyone who has reported an AHI. The IFR refers to only those from 2016 to the present because, as defined in the Act, only incidents that occurred on or after January 1, 2016, are eligible for payment. The Department maintains a list of all reported incidents; that list is not time-limited.

In the event of an adverse decision on a request for payment under the HAVANA Act, the Department has established an appeals process by which an individual may request further consideration.

5. Length of Qualifying Medical Treatment: Nine comments provided feedback on the length of qualifying medical treatment criteria. All comments disagreed that 12 months of qualifying medical treatment should be a requirement, with several suggesting that the time period be shorter – for example, three months instead of 12 months. Some proposed that the 12 months of treatment be replaced with other criteria, citing examples such as, receiving prescription medication or therapy for brain injury-related conditions such as migraines, vertigo, vision problems, and hearing loss. Another commenter suggested that the required 12 months of medical treatment be replaced with language that the “demonstrated effect of injury” was expected to last more than 12 months. The same comment expressed concern that covered employees who have been evaluated, but not yet had access to treatment, would not qualify otherwise and are excluded.

Individuals may be eligible for a HAVANA Act payment if they meet one of three criteria under the definition of “qualifying injury to the brain”: (1) an acute injury to the brain, such as, but not limited to, a concussion or penetrating injury, or as a consequence of an event that leads

to permanent alterations in brain function as demonstrated by confirming correlative findings on imaging studies (to include computer tomography scan (CT) or MRI) or EEG; or (2) a medical diagnosis of a traumatic brain injury (TBI) that required active medical treatment for 12 months or more; or (3) acute onset of new persistent, debilitating neurologic symptoms as demonstrated by confirming correlative findings on imaging studies (to include CT or MRI), or EEG, or physical exam, or other appropriate testing and that required active medical treatment for 12 months or more.

Of those three criteria, only (2) and (3) require 12 months of treatment, which would demonstrate that the individual suffers from a chronic condition.

Even if a covered individual has not yet received 12-months or more of treatment as outlined in (2) or (3), the covered individual may nevertheless qualify at a later time if treatment lasts for twelve months or more. Such individuals are not excluded but will have to meet the criteria to be eligible for a payment.

6. Payment eligibility criteria: Thirty-three comments discussed various aspects of the payment eligibility criteria. The majority of the comments expressed concern about who was eligible for payments. Another subset of comments questioned how eligibility is to be (or can be) determined without a clear definition or known cause of AHI. An additional comment raised a question about adequate funding for payments under the Act. The Department anticipates that resources will be available to provide payments to those who meet the eligibility criteria. One commenter asked what would happen if the Department underestimated the costs needed to pay all eligible requesters. The Department anticipates that resources will be available to provide payments to those who meet the eligibility criteria.

Fourteen comments stated that the payment eligibility criteria should be expanded, challenged the scope of “covered individuals” defined in the Act, and specifically mentioned unpaid interns and Embassy Science Fellows as examples of persons who should be included. The Department agrees that the payment eligibility criteria should be expanded to include unpaid

interns and will consequently insert “students providing volunteer services under 5 U.S.C. 3111” after “Temporary Appointments” in the definition of “covered employee.” The Department believes that Embassy Science Fellows are also covered under the definition of “covered employee”, unless they are an employee of another Federal agency. In the latter case, the employing agency would be responsible for making a determination for payment and making a payment if qualified under that agency’s rules. Additionally, the definition of covered employee has no reference to nationality, and employees who are citizens of other countries may qualify if they otherwise meet the criteria for payment.

The State Department drafted the IFR in close coordination with the interagency and National Security Council. As contemplated by Congress, other Federal agencies will need to prepare their own rules for implementation of the HAVANA Act.

Another comment questioned the objective capability of the Department to determine eligibility and award payment and suggested that a neutral outside board do so instead. The Department disagrees. For each request for payment, the Department will rely on the submission from the independent board-certified physician who completed the Form DS-4316, as well as available information on the reported incident, including any investigations that may have been conducted.

One comment stated that bodily injuries caused by AHI should be eligible for payments under the Act. The Department notes that the HAVANA Act of 2021 specifically authorizes payments for qualifying “injuries to the brain,” not “bodily injuries”.

Another comment shared a belief that the Department should make HAVANA Act payments posthumously to family members who had died because of mental health issues, arguing that not enough investigation has been done into the impacts of AHI on mental health illness. The Department notes that the HAVANA Act of 2021 specifically authorizes payments for qualifying “injuries to the brain,” not for mental health illnesses.

Several comments pointed out that there was no definition for or known cause of AHI and asked how it would be possible to determine who would qualify under the HAVANA Act, which they viewed as too broad and susceptible to abuse. Conversely, multiple comments expressed concern that the medical requirements to show an injury to the brain were too stringent. In response, the Department notes that, recognizing that the nature of AHI includes a lack of consensus by the medical and scientific communities, the definition of “qualifying injury to the brain” in the IFR was written to be comprehensive, respect congressional intent, and allow the physician completing the Form DS-4316 to consider appropriate medical information and context.

Two comments proposed alternate/additional payment eligibility criteria under § 135.3, *Eligibility for payments by the Department of State*, including allowing covered employees who have a Department-approved reasonable accommodation to be eligible for a Base Plus HAVANA Act payment. One comment said that a medical retirement from the Department should be sufficient to qualify for a Base Plus HAVANA Act payment.

In response to these two comments, the Department notes that it developed the eligibility criteria for a Base Plus payment under § 135.3 of the rule to cover individuals who have no employment potential with or without a reasonable accommodation. The Department believes that the four separate options for meeting the criteria in § 135.3(e)(2) represent a fair and consistent approach to determining Base Plus payments. In addition, the Department has added approval for Social Security Insurance (SSI) benefits as one of the eligibility criteria for a Base Plus payment.

7. Qualifying Injury: The Department received 24 comments related to qualifying injury. Several comments noted that the IFR’s definition of “qualifying injury to the brain” was not an actual definition, was too broad, and was open to “vast” interpretation. They asked if multiple sclerosis, idiopathic tics, dementia, epilepsy, Parkinson’s, and several other medical conditions would qualify as an eligible injury. Other comments pointed out that traditional imagery is not

likely to accurately identify changes to the brain, and that other documentation should be accepted or required, including vestibular tests. Likewise, some comments asserted a belief that TBI was a required diagnosis to qualify (which is inaccurate). Others expressed fraud and abuse concerns as taxpayers on the potential monetary scope of payments under the Act. They stated their belief that AHIs were not real and noted that there is no International Classification of Diseases, Tenth Revision (ICD-10), diagnosis code for AHI. Therefore, there would be no way to ensure that prospective recipients had been affected by an AHI, as opposed to other causative factors.

Recognizing that the nature of AHI includes a lack of consensus by the medical and scientific communities, the definition of “qualifying injury to the brain” in the IFR was written to be comprehensive, respect congressional intent, and allow the physician completing the Form DS-4316 to consider appropriate medical information and context. “Acute onset of new persistent, disabling neurologic symptoms as demonstrated by confirming correlative findings on imaging studies (to include CT or MRI), or EEG, or physical exam or other appropriate testing...” recognizes that the board-certified physician who completes the Form DS-4316 may exercise their professional judgment as to what elements are relevant. An ICD-10 diagnosis code specifically for AHI is not necessary as payments are for qualifying injuries to the brain, which will have one or more relevant ICD-10 codes.

Another comment specifically focused on children of affected covered employees, who reportedly did not receive evaluation of a possible AHI when their parent(s) were medically evacuated as the result of a suspected AHI. The comment states the writer’s belief that dependents of AHI-affected employees should automatically qualify for a HAVANA Act payment without medical documentation, based on their parent(s)’ injury. The Department notes that eligibility for a HAVANA Act payment under the IFR requires a currently board-certified physician to make a determination based in part on medical documentation submitted to the physician by the requester, and to complete the Form DS-4316 for each requester. Children of

affected covered employees who may not have been evaluated at the time of the parent(s)' medevac may qualify for a payment if they meet the eligibility criteria.

The Department also notes that imagery is one of several means by which requesters can establish eligibility for payment, and that the certifying physician will consider all available medical documentation when assessing the requester's condition. A diagnosis of a TBI is a non-exclusive criterion to potentially demonstrate eligibility under the HAVANA Act, and there are other ways in which an individual may meet the medical requirement, as listed in the definition. Regarding the concern that the injury may have been caused by factors other than an AHI, the physician must certify that they do not "have evidence or otherwise believe that the [requester's] symptoms can be attributed to a pre-existing condition."

8. Personal Experience: Three comments shared detailed accounts of individual experiences. One comment expressed frustration that the Department of Defense has not implemented its policy or procedures regarding the HAVANA Act. Another comment shared the commenter's experiences related to clinician care for AHI. The third shared the commenter's AHI experience. The Department of State respects and recognizes the service of persons from numerous departments, agencies, and institutions, public and private, who are working or have worked to advance the interests of the United States. The Department's IFR only covers persons who were employed by the State Department and dependents of those persons when the reported AHI occurred. Other U.S. Federal Government agencies will need to complete their own rulemaking process to evaluate payment eligibility.

9. Other: The Department received three comments that provided input on issues that are outside the scope of this rulemaking, including recommendations/comments on compensating employees for lost career growth as a result of an AHI; a belief that the Department must work with the Department of Labor (Federal Employees' Compensation Act (FECA)) on FECA requirements for TBI; and speculation about directed energy weapons. One commenter took the opportunity to address another comment with which they disagreed. The Department also

received an email from an individual who felt that the Department's "product" was linking to their family's devices.

The Department has a process to compensate employees for demonstrated lost career growth as a result of an AHI. It was given this authority under previous legislation. The Department also works closely with the Department of Labor on FECA claims filed by its employees, but the Department of Labor sets the requirements for eligibility for FECA benefits.

Regulatory Analysis

Administrative Procedure Act

This rule is being published as a final rule. Because this rule is a matter relating to public benefits, it is exempt from the requirements of 5 U.S.C. 553. *See* 5 U.S.C. 553(a)(2). Since the rule is exempt from the entirety of section 553 pursuant to section 553(a)(2), the provisions of section 553(d) do not apply and the rule will be in effect upon publication.

Congressional Review Act

The Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget (OMB) has determined that this rule is not a major rule as defined by 5 U.S.C. 804 for the purposes of congressional review of agency rulemaking under the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801-808).

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of \$100 million in any year; and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Executive Order 13175 – Consultation and Coordination with Indian Tribal Governments

The Department has determined that this rulemaking will not have tribal implications, will not impose substantial direct compliance costs on Indian tribal governments, and will not pre-

empt tribal law. Accordingly, the requirements of Executive Order 13175 do not apply to this rulemaking.

Regulatory Flexibility Act: Small Business

The Department of State certifies that this rulemaking will not have an impact on a substantial number of small entities. A regulatory flexibility analysis is not required under the Regulatory Flexibility Act (5 U.S.C. 601, *et seq.*).

Executive Order 12866 and Executive Order 13563

The Department of State has provided this final rule to OMB for its review. OIRA has designated this rule as “significant” under Executive Order 12866. Potential causes of AHI are being investigated but remain unknown. Given the nature of the incidents, it is difficult to accurately estimate future incidents and numbers of individuals affected. The Department approved/obligated funds for five cases totaling \$796,025 by the expiration of Fiscal Year (FY) 2022 on September 30. This is below our previous FY 22 estimate of \$1,545,225 primarily because we did not begin accepting requests for payment until 45 days before the end of the fiscal year. For FY 2023, the estimated numbers are up to \$7.3 million for 47 people. The Department has also reviewed the rule to ensure its consistency with the regulatory philosophy and principles set forth in Executive Order 12866 and finds that the benefits of the rule (in providing mechanisms for individuals to obtain compensation for certain injuries) outweigh any costs to the public, which are minimal. The Department of State has also considered this rulemaking in light of Executive Order 13563 and affirms that this regulation is consistent with the guidance therein.

Executive Order 12988

The Department of State has reviewed this rule in light of Executive Order 12988 to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burden.

Executive Orders 12372 and 13132

This rule will not have substantial direct effect on the states, on the relationships between the National Government and the states, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132, it is determined that this rule does not have sufficient federalism implications to require consultations or warrant the preparation of a federalism summary impact statement. Executive Order 12372, regarding intergovernmental consultation on Federal programs and activities, does not apply to this regulation.

Paperwork Reduction Act

This rulemaking is related to an information collection for the Form DS-4316, “Eligibility Questionnaire for HAVANA Act Patients,” OMB Control Number 1405-0250. This collection was approved under an emergency authorization. After OIRA approved the changes, the DS-4316 has been revised in accordance with the supplemental IFR and this final rule. The Department published a 60-day notice on September 9, 2022 (87 FR 55456). No public comments were received. The Department published a 30-day notice on November 21, 2022 (87 FR 70887) and OIRA approved the information collection on January 13, 2023.

List of Subjects in 22 CFR Part 135

Federal retirees, Government employees, Health care.

Accordingly, for the reasons stated in the preamble, the interim rules adding and amending 22 CFR part 135, which were published on June 30, 2022 (87 FR 38981), and August 9, 2022 (87 FR 48444), are adopted as final with the following changes:

PART 135 – IMPLEMENTATION OF THE HAVANA ACT OF 2021

1. The authority citation for part 135 continues to read as follows:

Authority: 22 U.S.C. 2651a; 22 U.S.C. 2680b.

2. Amend § 135.2 as follows:

- a. By revising paragraph (2) of the definition of “Covered employee” and paragraph (2) of the definition of “Qualifying injury to the brain”; and
- b. By placing the definition of “Other incident” into alphabetical order.

The revisions read as follows:

§ 135.2 Definitions.

* * * * *

Covered employee. * * *

(2) The following are considered employees of the Department (see procedures in 3 FAM 3660 and its subchapters) for the purposes of this part: Department of State Foreign Service Officers; Department of State Foreign Service Specialists; Department of State Civil Service employees; Consular Affairs – Appointment Eligible Family Member Adjudicator positions; Expanded Professional Associates Program members; Family Member Appointments; Foreign Service Family Reserve Corps; employees on Limited Non-Career Appointments; Temporary Appointments; students providing volunteer services under 5 U.S.C. 3111; personnel on a Personal Services Contract; Locally Employed Staff, whether employed on a Personal Services Agreement, Personal Services Contract, or appointed to the position; and Embassy Science Fellows, unless they are an employee of another Federal agency.

* * * * *

Qualifying injury to the brain. * * *

- (2) The individual must have:
 - (i) An acute injury to the brain such as, but not limited to, a concussion, penetrating injury, or as the consequence of an event that leads to permanent alterations in brain function as demonstrated by confirming correlative findings on imaging studies (to include computed tomography scan (CT) or magnetic resonance imaging scan (MRI)) or electroencephalogram (EEG); or

(ii) A medical diagnosis of a traumatic brain injury (TBI) that required active medical treatment for 12 months or more; or

(iii) Acute onset of new persistent, disabling neurologic symptoms as demonstrated by confirming correlative findings on imaging studies (to include CT or MRI), or EEG, or physical exam, or other appropriate testing, and that required active medical treatment for 12 months or more.

3. Amend § 135.3 by revising paragraphs (a) through (c) and (e)(2) to read as follows:

§ 135.3 Eligibility for payments by the Department of State.

(a) The Department of State may provide a payment to covered individuals, as defined in this part, if the qualifying injury to the brain was assessed and diagnosed in person by a currently board-certified physician from the American Board of Psychiatry and Neurology (ABPN), the American Osteopathic Board of Neurology and Psychiatry (AOBNP), the American Board of Physical Medicine and Rehabilitation (ABPMR), or the American Osteopathic Board of Physical Medicine and Rehabilitation (AOBPMR); occurred on or after January 1, 2016; and while the individual was a covered employee of the Department.

(b) The Department of State may provide a payment to covered employees, as defined in this part, if the qualifying injury to the brain was assessed and diagnosed in person by a currently board-certified physician from the ABPN, AOBNP, ABPMR, or AOBPMR; occurred on or after January 1, 2016; and while the employee was a covered employee of the Department.

(c) The Department of State may provide a payment to a covered dependent, if the qualifying injury to the brain was assessed and diagnosed in person by a currently board-certified physician from the ABPN, AOBNP, ABPMR, or AOBPMR; occurred on or after January 1, 2016; and the dependent's sponsor was a covered employee of the Department at the time of the dependent's injury.

* * * * *

(e) * * *

(2) Whether the Department of Labor (Workers' Compensation) has determined that the requester has no reemployment potential; or the Social Security Administration has approved the requester for either Social Security Disability Insurance or Supplemental Security Insurance (SSI) benefits; or the requester's ABPN, AOBNP, ABPMR, or AOBPMR board-certified physician has certified that the individual requires a full-time caregiver for activities of daily living, as defined by the Katz Index of Independence of Daily Living.

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Kevin E. Bryant,

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Billing Code 4710-10

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